

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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| Applicant's or agent's file reference P207193PCT | FOR FURTHER ACTION | See item 4 below |
| International application No. PCT/NL2005/000230 | International filing date (<i>day/month/year</i>) 29 March 2005 (29.03.2005) | Priority date (<i>day/month/year</i>) 26 March 2004 (26.03.2004) |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | |
| Applicant BERREKLOUW, Eric | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 9 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Date of issuance of this report 26 September 2006 (26.09.2006) Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Nora Lindner</div> |
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PATENT COOPERATION TREATY

REC'D 24 OCT 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing **26 OCTOBER 2005**
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/NL2005/000230

International filing date (day/month/year)
30.03.2005

Priority date (day/month/year)
26.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61F2/24, A61F2/06, A61B17/11, A61B17/115, A61B17/064

Applicant
BERREKLOUW, Eric

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/NL2005/000230

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/NL2005/000230

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and Industrial
applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 31-34

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 31-34

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/NL2005/000230

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-30

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-------------------------------|
| Novelty (N) | Yes: Claims | 5,7-10,13-16,19-21,27,28 |
| | No: Claims | 1-4,6,11,12,17,18,22-26,29,30 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-30 |
| Industrial applicability (IA) | Yes: Claims | 1-30 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/NL2005/000230

Re Item IV.

The separate inventions/groups of inventions are:

group 1: (claims 1-30)

Assembly comprising a ring having anchoring elements comprising a memory material, an applicator provided with a carrier and an temperature influencing system for bending the anchoring elements from a fitting to an anchoring position

(problem: how to move the anchoring elements from the fitting to an anchoring position)

group 2: (claims 31-34)

Heart valve prosthesis comprising a ring, valve leaflets and anchoring pins which are adapted to move from a first to a second penetrated position

(problem: how to move anchoring pins from a first to a second penetrated position)

The present application lacks unity within the meaning of Rule 13.2 of the P.C.T. and are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The document EP-A-1088529 cited in the present search report discloses an assembly in the form of a heart valve comprising a ring having anchoring elements comprising a memory material, an applicator provided with a carrier and an temperature influencing system for bending the anchoring elements from a fitting to an anchoring position.

Over this prior art the special technical features (in the meaning of P.C.T. Rule 13.2) claimed in the application are:

Group 1: no special technical features

Group 2: anchoring pins which are adapted to move from a first to a second penetrated position.

No same or corresponding potential special technical feature can be found between any

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/NL2005/000230

two of the above mentioned subjects. There is therefore no technical relationship involving same or corresponding potential special technical features between two of these subjects. The inventions defined in the above mentioned subjects are thus not considered linked by a common inventive concept.

Re Item V.

1 Reference is made to the following documents:

- D1 : EP 1 088 529 A (SORIN BIOMEDICA CARDIO SPA) 4 April 2001 (2001-04-04)
- D2 : US 2003/149476 A1 (FIGULLA HANS-REINER ET AL) 7 August 2003 (2003-08-07)
- D3 : US 2002/029049 A1 (COSTA PETER F ET AL) 7 March 2002 (2002-03-07)
- D4 : EP 0 896 813 A (SORIN BIOMEDICA SPA) 17 February 1999 (1999-02-17)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (see paragraphs 15 - 21; paragraphs 44 - 49; figures; the references in parentheses applying to this document):

Assembly (88) comprising:

a ring (10) having anchoring elements (104) for attaching the ring in a passage surrounded by body tissue, in particular blood vessel tissue;
in which the anchoring elements (104) have an anchoring position in which they protrude outwardly with respect to the ring, and
in which the anchoring elements (104) comprise a memory material, such as a memory metal, and are designed so that they can be bent from an anchoring position counter to a spring force into a fitting position and can be frozen in this fitting position by a temperature treatment in order to bend the anchoring elements (104) back from the fitting position by the effect of this spring force into the anchoring position when a predetermined threshold temperature is exceeded; and

in which the applicator is provided distally with a carrier (*in form of a transport catheter with an expandable balloon*) for carrying the ring;

wherein,

the assembly (88) is provided with an influencing system for influencing the temperature of the anchoring elements (104) of the ring (10) carried by the carrier in such a way that the anchoring elements bend back from the fitting position to the anchoring position by increasing the temperature of the anchoring elements to above the threshold temperature.

2.2 The attention of the applicant is drawn to the fact that each of the documents D2 (see paragraphs 27 - 36; figures) and D3 (see paragraph 196; paragraph 106; paragraph 212; figures) discloses all the technical features of claim 1, and are prejudicial for its novelty as well.

3 DEPENDENT CLAIMS 2 - 30

3.1 Document D1 describes (see paragraphs 15 - 21; paragraphs 44 - 49; figures) in combination with the technical features of claim 1 also the features of claims 3, 4, 6, 22 - 25, 29 and 30. D2 describes (see paragraphs 27 - 36; figures) the features of claims 2, 17 and 18. D3 describes (see paragraph 196; paragraph 106; paragraph 212; figures) the features of claims 11, 12 and 26. Therefore, the subject-matter of claims 2 - 4, 6, 11, 12, 17, 18, 22 - 26, 29 and 30 is not new.

3.2 The features of dependent claims 5, 7 - 10, 13 - 16, 19 - 21, 27 and 28 are not disclosed in combination with the features of the claims on which they depend in any of the available prior art documents. Therefore, these claims meet the requirements of Article 33(2) PCT.

3.2.1 However, the features of claim 8 are used for the same purpose in D1 (see paragraphs 15 - 21; paragraphs 44 - 49; figures). Therefore, claim 8 does not fulfill the requirements of inventive step, Article 33(3) PCT.

3.2.2 The features in claims 5, 7, 9, 10, 13 - 16, 19 - 21, 27 and 28 are merely one of

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/NL2005/000230

several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed and therefore do not fulfill the requirements of Article 33(3) PCT.

3.3 The device described in the present claims is industrial manufacturable and therefore the requirements of Article 33(4) PCT are fulfilled.